Case **MPSCO-013B1**

HUBER NEEDLE WITH ANTI-REBOUND SAFETY MECHANISM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. Patent Application Serial No. 10/375,963 entitled "HUBER NEEDLE WITH ANTI-REBOUND SAFETY MECHANISM" filed February 28, 2003, which is a continuation-in-part of U.S. Patent Application Serial No. 10/350,765 entitled "HUBER NEEDLE WITH ANTI-REBOUND SAFETY MECHANISM" filed January 24, 2003, which claims the benefit of U.S. Provisional Application No. 60/360,406 entitled "HUBER NEEDLE WITH ANTI-REBOUND MECHANISM" filed February 28, 2002, the entirety of the disclosures of which are expressly incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

[0002] Not Applicable

BACKGROUND OF THE INVENTION

[0003] The present invention relates generally to medical needle devices, and more particularly to an improved, passive safety needle device featuring a sheath assembly which is designed to be outwardly deployable and enclose the exposed portion of an affixed needle therewithin so as to protect its user against inadvertent needle-stick injuries.

[0004] Needle-stick injuries are common and are of great concern in today's health-care industry. A vast majority of these injuries occur while withdrawing conventional Huber needles from implanted IV ports after administering medicants such as antibiotics or chemotherapy.

[0005] More specifically, a great deal of force is required during Huber needle withdrawal to overcome the resistance of the port's septum. Since a non-dominant hand is typically used in this process to secure the implanted port, it often becomes stuck on the rebound of the Huber needle.

[0006] Because a Huber needle is utilized for venous access, such needle-stick injury as described above presents a high risk for pathogen transmission. An exposed and/or injured

health-care worker must be tested for various blood-borne pathogens such as hepatitis B, hepatitis C and HIV.

[0007] Such testing is usually repeated to ensure that the exposed and/or injured health-care worker is not infected of those pathogens. As a further precaution, boosting of immunity may simultaneously take place as an additional insurance of safety.

[0008] In order to alleviate the dangers associated with needle-stick injuries, some health-care workers have fashioned home-made guards to protect their non-dominant hands. However, these home-made guards are not user-friendly as the health-care workers must make the conscious choice to wear them every time an injection is made.

[0009] The health-care workers may sometimes neglect to put them on because they are either inconvenient to use, interfere with the process of administering the Huber needle or the health-care workers may just simply forget to wear them. All of these factors contribute to negating the guards' effectiveness to protect the health-care workers against the dangers of needle-stick injuries.

[0010] In view of the above-described shortcomings of conventional needle guards, there exists a need in the art for a safety needle guard which can protect health-care workers against the dangers of needle-stick injuries in a convenient and user-friendly manner. More specifically, there exists a need for a safety needle guard which can be automatically implemented in a user passive manner during the needle injection process so as to consistently protect the health-care workers against the dangers of needle-stick injuries.

BRIEF SUMMARY OF THE INVENTION

[0011] The present invention specifically addresses and alleviates the above-referenced deficiencies associated with the use of the Huber needle guards of the prior art. More particularly, the present invention is an improved, passive safety needle device featuring a sheath assembly which is outwardly deployable relative to the exposed portion of its affixed needle. By such deployment, a physical barrier can be placed around the needle by the sheath assembly to protect a user from being inadvertently stuck by the needle, thus preventing needle-stick injuries and all the risks that are associated with them. Although this sheath assembly is intended to be used for Huber needle applications, it is specifically recognized herein that such sheath assembly may be used in conjunction with other types of conventional needle applications as well.

[0012] In accordance with a preferred embodiment of the present invention, there is provided a passive safety needle device for protecting its user against a needle-stick injury. The safety needle device of the present invention first features a needle housing comprised of two substantially identical housing halves engaged to each other about their respective inner housing faces. Although such housing halves may be engaged in any manner or fashion, it is preferred that such engagement occurs through ultrasonic welding. Moreover, each of the two housing halves are preferably fabricated from a plastic material such as through the process of plastic injection molding.

[0013] The needle housing includes an internal groove which is elongated therewithin and communicates with its distal opening. This groove is preferably elongated in a manner as to substantially correspond to (i.e., be complementary to) the general arcuate curvature of the needle housing's upper surface. In this respect, the internal groove defines a bend radius which is complementary in shape to the upper housing surface.

[0014] In the preferred embodiment of the present invention, the needle housing further includes a needle, of which its intermediate portion is disposed within the elongated groove. In this regard, that portion of the needle is formed in an arcuate configuration to match the bend radius of the groove so it can be accommodated therewithin. The needle utilized with the present needle device is preferably a stainless steel Huber needle having a non-coring distal needle point.

[0015] The needle defines a proximal needle portion which becomes exposed outside of the needle housing by extending through the needle housing's proximal opening. Flexible infusion tubing preferably made from silicone rubber and/or polyvinyl chloride or polyethylene surrounds this exposed proximal portion of the needle and connects to the needle housing through its proximal opening. The infusion tube or tubing can be maintained in this position by the engagement of the two housing halves which compress on the tubing.

[0016] A distal portion of the needle is defined generally opposite to the proximal needle portion. The needle portion is retained outside of the needle housing as it is extended downward through the distal housing opening. The distal needle portion forms a needle point at its exposed end which is used for penetrating the patient's skin and accessing the implanted port.

[0017] In the preferred embodiment, the needle housing has a lower housing surface that defines a lower housing recess. This recess is primarily intended for accommodating a hold-

down platform. The hold-down platform may be engaged within the recess through a variety attachment procedures such as adhesive or fastener. By providing platform strips which radially extend outward from such location of engagement, the hold-down platform may be placed near the injection point and be used for securing the safety needle device upon the patient by means of taping over the platform strips and the patient's skin. Preferably, the hold-down platform has a generally circular or rectangular configuration, and is fabricated from either a rubber or plastic material.

[0018] In accordance with a preferred embodiment of the present invention, an elongate sheath assembly is provided within the needle housing. More specifically, this sheath assembly is situated within the groove when disposed in a retracted position surrounding the intermediate portion of the needle. The sheath assembly has an axial length that is substantially identical to that of the elongated groove. Although the sheath assembly may be formed from various materials, it is preferably formed as an elongate wound stainless steel wire tube and/or semi-rigid polymer such as polyethylene or Teflon.

[0019] The sheath assembly of the preferred embodiment defines a distal sheath end. Attached to this end is a distal tip component which preferably comprises a transparent plastic tip. The tip component can be either insert molded or adhered to the distal sheath end. The distal tip component forms a distal tip having a diameter which is generally greater than that of the groove but substantially equal to or less than the diameter of the distal housing opening.

[0020] The sheath assembly further defines a proximal sheath end generally opposite to the distal sheath end. Attached to the proximal sheath end is a proximal tip component having a diameter which is generally greater than the diameter of the groove's distal opening. As will be discussed more fully below, such configuration allows the sheath assembly to stop once reaching the fully extended position, that is, the distal tip component being advanced over and beyond the distal needle point while enclosing the distal needle portion with the sheath assembly. Although other types of tip components may be contemplated, the proximal tip component utilized with the present invention is preferably formed as a stainless steel or plastic ferrule.

[0021] In the preferred embodiment of the present invention, a biasing member is provided within the needle housing. This biasing member is used for passively moving the sheath assembly along the groove between the retracted and extended positions. The biasing member is

connected between the proximal tip component and a knob member disposed on the exterior of the needle housing.

[0022] The knob member allows the user to control the movement of the sheath assembly along the elongated groove. This is possible due to the mechanical connections with the proximal tip component of the sheath assembly and the biasing member. Because the preferred biasing member comprises a torsional biasing member which is configured to naturally urge the sheath assembly towards the extended position, the user may utilize the knob member to control the sheath assembly when moving along that direction. In the preferred embodiment, the biasing member comprises either a torsional arm or torsional spring. However, other types of biasing members are contemplated as they may also achieve the ultimate objective of passively deploying the sheath assembly outwardly with respect to the distal needle portion.

[0023] In accordance with a second preferred embodiment of the present invention, a passive safety needle device of modified structure is disclosed herein. This specific safety needle device is essentially designed to perform the same function as that of the above-described needle device through the use of a modified structural configuration. More specifically, it utilizes a different type of proximal tip component at the proximal sheath end for moving the sheath assembly along the groove.

[0024] In lieu of using a ferrule as the proximal tip component, the alternately configured needle device comprises a tip body which is preferably fabricated through plastic molding. Although other forms of attachment are contemplated herein, the tip body is preferably barb fitted through the proximal sheath end of the sheath assembly. This enables the tip body to be fixedly secured to the sheath assembly which allows it to transition along the groove when the tip body is urged by the biasing member (e.g., torsion spring) to move therealong.

[0025] The tip body is releasibly mounted upon a trigger member which is structurally configured to be elongated from within the needle housing to the outside thereof. In particular, the tip body is designed to maintain the sheath assembly in the retracted position against the force of the biasing member. To accomplish this, the trigger member extends a tip retaining projection through the tip body from its end which is disposed within the needle housing. Its opposite end is exposed through the needle housing and serves as a trigger mechanism for passively moving the tip body, and hence the sheath assembly, from the retracted position to the extended position. More particularly, the trigger member maintains the tip body and the sheath

assembly in the retracted position until the tip body is manually released from the tip retaining projection. Such release of the tip body is performed by pressing the exposed end of the trigger member towards the needle housing. This causes the tip retaining projection to slip out from the tip body and free the tip body from its holding. Due to its connection with the biasing member which applies force towards the extended position, the tip body is automatically caused thereby to be moved in that direction, hence effectuating the same directional movement of the sheath assembly as well.

[0026] Similar to the above-described proximal tip component, the tip body possesses a body size which is substantially larger than the distal opening of the groove. This allows the tip body to stop once reaching and abutting the portion of the groove forming the narrowed distal opening. Upon reaching such positioning, the sheath assembly should now be deployed outside of the needle housing and be extended over the entirety of the needle's distal portion, including its tip. The sheath assembly is projected to remain outwardly deployed since the spring force applied by the biasing member would urge the tip body against the converged portion of the groove which forms its distal opening.

[0027] In accordance with a third preferred embodiment of the present invention, a different version of the passive safety needle device is described herein. This version of the safety needle device is also designed to perform the same function as the needle devices of the first and second embodiments. However, the third embodied needle device employs the use of a wholly different sheath releasing concept in doing so. More particularly, it eliminates the need for any type of proximal tip component such as a ferrule (as used in the first preferred embodiment) or a tip body (as used in the second preferred embodiment) at the proximal sheath end for retaining, releasing and moving the sheath assembly along the groove.

[0028] Rather, the safety needle device of the third embodiment utilizes an extension of its biasing member (e.g., torsional arm) to connect directly to the proximal end of the sheath assembly. Specifically, such extension extends out from the biasing member substantially parallel to the inner housing surfaces of the needle housing. Upon reaching the proximate location of the proximal sheath end, an end portion of the biasing member's extension is curved or bent toward the proximal sheath end, preferably forming a generally perpendicular relationship with the inner housing surfaces. That end portion is then ultimately connected through the proximal sheath end of the sheath assembly.

[0029] In particular, the extension's end portion is inserted through one side of the proximate sheath end and is allowed to come out of the generally opposing side thereof. This allows the extension to be connected to the proximate sheath end, thereby placing the biasing member in mechanical connection with the sheath assembly. Preferably, the end portion of the extension is curved or bent backward in the general direction of the biasing member so as to prevent it from inadvertently slipping out or disconnecting from the proximal sheath end unless the proximal sheath end somehow becomes torn or ruptured.

[0030] Similar to the second embodiment, the safety needle device of the third embodiment utilizes a trigger member for retaining and releasing the sheath assembly. Like the version described in the second embodiment, the trigger member utilized in the third embodiment has one end disposed within the needle housing and an opposite end disposed outside the needle housing. Essentially, this trigger member is also operative to release the retained sheath assembly via pressing the exposed outside end thereof towards the needle housing. Upon such action, the torsional force of the biasing member causes the sheath assembly to be automatically moved toward the extended position.

[0031] However, the tip retaining projection formed adjacent the internally located end of the trigger member is structurally different from the version illustrated in the second embodiment. In particular, the tip retaining projection directly engages the end portion of the biasing member's extension when the extension and proximal sheath end are retracted back in the retracted position. More particularly, the tip retaining projection of the third embodiment extends upward and away from the internally located end of the trigger member.

[0032] Formed at the projected end of the tip retaining projection is its engaging portion which directly engages the end portion of the biasing member. The engaging portion is positioned generally perpendicular to the projected end of the tip retaining projection and comprises a notch which faces toward the trigger member. This notch is used for releasibly engaging the end portion of the biasing member's extension until the trigger member is manually pressed. More specifically, the notch of the engaging portion preferably hooks a section of the extension's end portion which is defined either prior or subsequent to the insertion into proximal sheath end. In the preferred embodiment, the notch has a smooth and continuous surface so that the extension's end portion may be easily dislodged therefrom when the trigger member is

pressed inward by the user's finger, hence deploying the sheath assembly outside the needle housing.

[0033] Upon the outward deployment of the sheath assembly, the proximate sheath end is designed to stop once reaching the distal opening of the needle housing's groove. This is possible because the extension of the biasing member will come in contact with the lower inner housing surface of the needle housing and be forced to stop its movement upon such contact. Due to its engagement to the proximal sheath end, the extension in turn forces the proximal sheath end to stop its movement about the distal opening. This results in the sheath assembly to be deployed outside the needle housing and be extended over the entirety of the needle's distal portion, including its tip. The sheath assembly should remain outwardly deployed as the spring force of the biasing member urges the extension tightly against the lower inner housing surface of the needle housing.

[0034] The operation of the safety needle device of the first embodiment is described herein to illustrate the operation of the safety needle device of the second and third embodiments as well. The safety needle device of the first embodiment is designed to protect a user from inadvertent needle stick during withdrawal of the needle from the patient. More specifically, the distal needle point is first injected into a designated skin area of the patient to access the implanted IV port. By such penetration, various tasks such as delivering fluids and medications, drawing blood for diagnostic testing and/or infusing blood products may be conducted. Optionally, the needle device can be secured in place by taping its platform strips to the patient's surrounding skin area.

[0035] After performing any one of the tasks as described above, the needle is withdrawn from the patient. While withdrawing the needle, the sheath assembly is deployed outwardly and passively from within the needle device relative to the distal needle portion resulting in the distal needle portion being completely enclosed and/or surrounded by the outwardly deployed sheath assembly. Such process can be facilitated by using the externally located knob member which allows the user to control the outward deployment of the sheath assembly. In the case of the second or third embodied safety needle device, the trigger member can be manually pressed inward to automatically trigger the outward deployment of the sheath assembly.

[0036] The needle device is then ready for proper disposal in a Sharps container or other container designated for used medical devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] These as well as other features of the present invention will become more apparent upon reference to the drawings wherein:

[0038] Figure 1 is a perspective view of a safety needle device constructed in accordance with a preferred embodiment of the present invention and illustrating its needle housing having generally rectangular platform strips radially extending outward therefrom;

[0039] Figure 2 is a perspective cross-sectional view of the safety needle device of Figure 1 and illustrating the manner in which a sheath assembly is extended from within its needle housing;

[0040] Figure 3 is a side cross-sectional view of the safety needle device of Figure 1 illustrating the manner in which a sheath assembly is retracted within its needle housing;

[0041] Figure 4 is a side view of the safety needle device of Figure 1 and illustrating a needle's exposed distal portion which extends downward out of its needle housing;

[0042] Figure 5a is a top view of the safety needle device of Figure 1 illustrating the flexible infusion tubing which is connected through a proximal opening of its needle housing;

[0043] Figure 5b is an enlarged view of the encircled portion of Figure 5a, illustrating a proximal notch which is used for retaining a sheath assembly in a retracted position;

[0044] Figure 6a is a front view of the safety needle device of Figure 1 illustrating a needle's distal portion which is disposed generally perpendicular to the radially extending platform strips;

[0045] Figure 6b is an enlarged view of the encircled portion of Figure 6a, illustrating a distal notch which is used for securing a sheath assembly in an extended position;

[0046] Figure 7a is a side view of a needle having a bent intermediate portion which corresponds to the configuration of an elongate groove formed within the needle housing of Figure 1;

[0047] Figure 7b is a partial side view of the needle of Figure 7a and illustrating its distal portion which defines a non-coring pointed end;

[0048] Figure 8a is a front perspective view of a torsional arm which is used for moving the sheath assembly of Figures 2 and 3 between the retracted and extended positions;

[0049] Figure 8b is a top view of the torsional arm of Figure 8a and illustrating the direction in which it bends when being inserted within proximal and distal notches of the needle housing;

[0050] Figure 8c is a side view of the torsional arm of Figure 8a illustrating the direction in which it bends when the sheath assembly is moved between the retracted and extended positions;

[0051] Figure 9a is a side view of one housing half which is used to form the needle housing of Figure 1 when engaged with the other housing half;

[0052] Figure 9b is a perspective view of the housing half of Figure 9a illustrating pegs formed about an inner housing face thereof;

[0053] Figure 9c is a top view of the housing half of Figure 9a illustrating its upper housing surface forming a proximal notch;

[0054] Figure 9d is a rear view of the housing half of Figure 9a illustrating its side housing surface forming finger-graspable projections;

[0055] Figure 10 is a perspective cross-sectional view of the sheath assembly of Figures 2 and 3 illustrating its proximal and distal tip components;

[0056] Figure 11 is a perspective view of the safety needle device of Figure 1 and illustrating its needle housing which uses generally half-circular platform strips as an alternative to the generally rectangular platform strips;

[0057] Figure 12 is a side cross-sectional view of the safety needle device of Figure 11 illustrating the use of a torsional spring as an alternative to the torsional arm;

[0058] Figure 13 is an exploded perspective view of a safety needle device constructed in accordance with a second preferred embodiment of the present invention and illustrating its needle housing having generally half-circular platform strips extending outwardly therefrom;

[0059] Figure 14 is a side view of the safety needle device of Figure 13 and illustrating the manner in which its tip body is barb fitted through an end of the sheath assembly;

[0060] Figure 15 is a perspective view of the safety needle device of Figure 13 and illustrating its trigger member which retains the tip body and the sheath assembly in a retracted position;

[0061] Figure 16 is a perspective view of the safety needle device of Figure 13 and illustrating its needle housing which portrays an alternate outer configuration than the one shown in Figure 13;

[0062] Figure 17 is an exploded perspective view of a safety needle device constructed in accordance with a third preferred embodiment of the present invention and illustrating its needle housing which includes a layer of padding thereunder;

[0063] Figure 18 is a side view of the safety needle device of Figure 17 and illustrating the manner in which its biasing member is engaged through an end of the sheath assembly; and

[0064] Figure 19 is a perspective view of the safety needle device of Figure 17 and illustrating its trigger member which retains the biasing member and the sheath assembly in a retracted position.

DETAILED DESCRIPTION OF THE INVENTION

[0065] Referring now to the drawings wherein the showings are for purposes of illustrating preferred embodiments of the present invention only, and not for purposes of limiting the same, Figure 1 illustrates a passive safety needle device 10 constructed in accordance with a preferred embodiment of the present invention. As indicated above, the present safety needle device 10 features a sheath assembly 12 which is outwardly deployable with respect to the distal needle portion 14, that is, the exposed portion of its affixed needle 16 which is used to access an IV port implanted underneath a patient's designated skin area (not shown).

[0066] As will be soon discussed, such passive deployment of the sheath assembly 12 provides a tangible physical barrier around the distal needle portion 14 to protect a user from being inadvertently stuck by the needle 16, thereby preventing needle-stick injuries and all the risks associated therewith. Although the sheath assembly 12 is preferably used for Huber needle applications, it is expressly contemplated herein that such sheath assembly 12 may be used for other types of conventional needle applications as well.

[0067] Referring more particularly to Figures 1 and 9a-9c, the safety needle device 10 includes a needle housing 18. Although this needle housing 18 may be formed from a unitary construction, it is preferably constructed from two substantially identical housing halves 20, 22 which are assembled to each other about their respective inner housing faces 24. The first housing half 20 includes at least one peg 26 that can be retained within at least one corresponding aperture (not shown) provided on the second housing half 22. The permanent engagement between the two housing halves 20, 22 is preferably accomplished with adhesive or ultrasonic welding or snap fit engagement.

[0068] The two substantially identical housing halves 20, 22 may be fabricated from any rigid material. However, the material of choice is a polymer (i.e., plastic). In this respect, the

manufacture of each housing half 20 or 22 may be greatly expedited through utilizing the process of plastic injection molding techniques.

[0069] Referring now to Figures 9d and 11, the exterior of the needle housing 18 preferably includes plural projections 30 to ease in the handling of the present safety needle device 10. These projections 30 may be formed on one or both sides 32 of the needle housing 18. As can be seen from the specified figures, the finger-graspable projections 30 may be provided as a group of linearly configured projections (as shown in Figure 9d) or arcuately configured projections (as shown in Figure 11).

[0070] As shown in Figures 2 and 4, the needle housing 18 includes an internal arcuate groove 34 which initiates intermediate the housing and extends to a distal opening 36 of the needle housing 18. Preferably, the groove 34 is formed in a generally complementary configuration to the general arcuate curvature of the needle housing's upper surface 38. As such, the internal groove 34 has a bend radius which closely simulates the bend radius of the upper housing surface 38.

[0071] The needle housing also contains a needle 16, of which an intermediate portion 40 thereof is disposed within the elongated groove 34. The intermediate needle portion 40 is sufficiently formed (i.e., bent to closely match the bend radius of the internal groove 34 so as to be accommodatingly disposed therewithin). The needle 16 preferably used with the present safety needle device 10 comprises a stainless steel Huber needle. However, other types of needles such as a conventional hypodermic syringe needle may be workable with the present safety needle device 10. Preferably, the needle 16 has a needle point 42 which is non-coring but use of the coring needle point may be contemplated. Of course, the needle point 42 is intended for penetrating a designated area of the patient's skin and accessing an IV port implanted underneath.

[0072] Figures 2 and 3 show a proximal needle portion 44 of the needle 16. The proximal needle portion 44 is exposed outside of the needle housing 19 by extending through a proximal opening 46 thereof. This needle portion 44 is connected to a flexible infusion tube or tubing 48, in one end 50 of which is rigidly connected to the needle housing 18 through its proximal opening 46. The other end (not shown) of the infusion tubing is typically placed in communication with a conventional syringe or an infusion pump (not shown).

[0073] Referring specifically to Figures 9a and 9b, needle-retaining projections 52 are preferably formed adjacent the proximal opening 46. These projections 52 provide an interference and mechanical lock on the tubing 48 when the two housing halves 20, 22 are assembled. Moreover, the portion of the needle 16 which lies between the groove 34 and the proximal opening 46 may be secured in place through the use of a fitting track 54 or adhesive.

[0074] As shown in Figures 3 and 7a-7b, a distal needle portion 14 is provided generally opposite to the proximal needle portion 44. The distal needle portion 14 is exposed outside of the needle housing 18 extending downwardly through the distal housing opening 36. As briefly mentioned above, this portion 14 forms a needle point 42 at its exposed end which is used for penetrating the patient's skin and accessing the implanted subcutaneous IV port.

[0075] Referring now to Figures 1, 2, 6a and 11, the needle housing 18 has a lower housing surface 56 which defines a recess 58 underneath. This lower housing recess 58 is utilized for accommodating a hold-down platform 60. More specifically, the hold-down platform 60 is maintained within the recess 58 by various conventional attachment means (i.e., adhesive, fasteners, or the like).

[0076] The hold-down platform 60 features at least two platform strips 62 which radially extend out from the needle housing 18. In this respect, the platform strips 62 are disposed in a manner as to form a generally perpendicular relationship with the distal needle portion 14. The hold-down platform 60 is primarily used to secure the safety needle device 10 upon the patient while infusion takes place by means of taping over the platform strips 62 and the patient's skin. The platform 60 may be fabricated from any rigid or semi-rigid material such as plastic or rubber. In one configuration, the hold-down platform 60 is formed having a generally circular configuration (best shown in Figure 11). In the other configurations, it is formed having a generally rectangular configuration (best shown in Figure 1).

[0077] Figures 2, 3 and 10-12 depict an elongate sheath assembly 64 and illustrates its ability to move from within to and out of the needle housing 18. In particular, the elongate sheath assembly 64 is disposed in a retracted position designated by the numeral 66 within the internal groove 34 of the needle housing 18 in a manner as to surround the intermediate needle portion 40. The assembly 64 has a longitudinal length that is substantially equal or somewhat longer than the arcuate length of the internal groove 34. Obviously, the sheath assembly 64 has a diameter which is less than that of the groove 34 so as to allow its axial movement therewithin.

Although the sheath assembly 64 may be formed from various materials, it is preferably made from an elongated wound wire constructed of stainless steel (as shown in Figure 10).

[0078] The sheath assembly 64 includes a distal end 68 which mounts to a distal tip component 70. Preferably, the distal tip component 70 is fabricated from a plastic, preferably transparent, material. However, the distal tip component 70 should in no way be limited to such construction as other forms of rigid or semi-rigid tips (e.g., metal or rubber tips) may be used in lieu thereof. The distal tip component 70 is attached to the distal sheath end 68 either through the process of insert molding or adhesive. The tip component 70 may include a distal tip 72 having a diameter size generally greater than that of the groove's distal opening 78, but substantially equal to or lesser than the diameter of the distal housing opening 36 (as shown in Figure 3). Alternatively, the diameter of the distal tip 72 may be sized to be somewhat similar to the diameter of the distal groove opening 78 (as shown in Figure 11).

[0079] The sheath assembly 64 further includes a proximal sheath end 74 which is located generally opposite to the distal sheath end 68. A proximal tip component 76 is attached to the proximal sheath end 74. Similar to the distal tip component 70, the proximal tip component 76 can be attached via insert molding or adhesive. The tip component 76 has a diameter size which is generally greater than the diameter of the groove's distal opening 78. Such diameter size of the proximal tip component 76 facilitates stopping the sheath assembly 64 once it has reached its fully extended position designated generally by the numeral 80 (i.e., the distal tip component 70 being advanced over and beyond the distal needle point 42 while enclosing the distal needle portion 14 with the sheath assembly 64). Although other types of tip components may be used, the proximal tip component 76 is preferably fabricated as a stainless steel or plastic ferrule.

[0080] Referring now to Figure 2, 3, 8a-8c and 12, the needle housing 18 includes a biasing member 82 therewithin. This biasing member 82 is secured in place within its allocated track 84 which prevents it from bending. A blind hole 86 is also provided as a further insurance in securing the biasing member 82. Cored-out pockets 88 are defined about the biasing member 82 in order to maintain a constant wall thickness. A top projection 90 is also provided on each of the housing halves 20, 22 to resist squeezing the track 84 together and to prevent the free movement of the biasing member 82 when removing the needle 16 from the patient. The biasing member 82 is used for moving the sheath assembly 64 along the groove 34 between the retracted

and extended positions 66, 80. This can be accomplished through its engagement to the proximal tip component 76 and to an outwardly exposed knob member 92.

[0081] The knob member 92 is provided external to the needle housing 18 and allows the user to manually and passively control the movement of the sheath assembly 64 along the elongated internal groove 34.

[0082] More specifically, an extension 94 of the biasing member 82 is connected to a recess 96 (shown in Figure 10) formed on the proximal tip component 76. The biasing member's extension 94 forms a circular bend portion 95 which extends around the proximal tip component's recess 96. The extension 94 further extends out and attaches to the knob member 92 via insert molding or adhesive. Due to the torsional spring property of biasing member 82 which naturally urges the sheath assembly 64 toward the extended position 80, the user may utilize the knob member 92 to control the sheath assembly 64 when passively moving from its retracted to extended position.

[0083] The biasing member 82 is preferably fabricated from a resilient material such as stainless spring steel or Nitinol. Due to such elastic nature, the extension 94 of the biasing member 82 is capable of bending vertically when the sheath assembly 64 is moved between the retracted and extended positions 66, 80 (best shown in Figure 8c). As illustrated in Figure 8b, it can even bend sideways when the extension 94 is snapped into the proximal notch 98 (for maintaining the retracted position 66) or into the distal notch 100 (for maintaining the extended position 80). The biasing member 82 used with the present safety needle device 10 can take the form of a torsional arm or a torsional spring.

[0084] Referring now to Figures 13 and 16, there is shown a passive safety needle device 110 which is constructed in accordance with a second preferred embodiment of the present invention. The alternately embodied safety needle device 110 is essentially designed to perform the same function as that of the above-described needle device 10, that is, to passively extend its sheath assembly 122 over the distal portion 114 of the needle 116 (i.e., Huber needle), and hence provide effective protection against dangers of needle-stick injuries. However, it accomplishes such objective through a structural configuration which is somewhat different than the one disclosed above.

[0085] First, although the safety needle device 110 of the second embodiment may utilize a similar or identical needle housing 18 as described above, it may alternatively display its own

unique type of needle housing 118 which is aesthetically different therefrom. Such needle housing 118 is exemplified in Figure 16 and as can be seen from that figure, its outer shape or configuration is substantially similar as its counterpart shown in Figure 11. One major difference between them, however, is that the needle housing 118 of Figure 16 eliminates the need for any finger-graspable projections 30 and rather provides a substantially continuous and smooth outer surface in lieu thereof. Furthermore, the needle housing 118 is preferably fabricated from a plastic material and may optionally characterize a transparent or semi-transparent body.

[0086] As illustrated in Figures 14 and 15, the safety needle device 110 of the second embodiment additionally utilizes a different type of proximal tip component 126 for passively moving the sheath assembly 122 out of the groove 124 and over the needle 116. Instead of using a ferrule as the proximal tip component 76, the alternative safety needle device 110 utilizes a specially manufactured tip body 126 in its place (best shown in Figure 15). Although this tip body 126 may be fabricated from any rigid material, it is preferably made through plastic molding.

[0087] The tip body 126 is attached to the sheath assembly 122 at its proximal sheath end 128. It is contemplated herein that the tip body 126 may become attached to the proximal sheath end 128 by various methods of attachment such as fastening or adhering. Preferably, however, the tip body 126 is attached through barb fitting method. More particularly, the tip body 126 defines a tip protrusion 130 which is extended through and pressed into the proximal sheath end 128 of the sheath assembly 122. Such barb fitting of the tip protrusion 130 into the proximal sheath end enables the tip body 126 to be securely affixed to the sheath assembly 122 thereat. This in turn allows the sheath assembly 122 to passively transition along the groove 124 and be deployed outside of the needle housing 118 when the tip body 126 is caused to move in that direction by the biasing member 132 that it is connected to. Although other types of biasing members 132 such as a torsional arm may be utilized for this purpose, it is preferred that a torsional spring is used as the biasing member 132 of the alternately embodied safety needle device 110 (shown in Figure 15).

[0088] The specially manufactured tip body 126 is releasibly mounted upon a trigger member 134 which is specifically designed for the purpose of retaining and releasing the tip body 126. In order to accomplish such objective, the trigger member 134 possesses a structural

configuration which is sufficient to be elongated from within the needle housing 118 to the outside thereof. Although the trigger member 134 may be variously configured and/or shaped, it is preferably elongated in a bar-like configuration. Such configuration of the trigger member 134 facilitates in maintaining the tip body 126 in place against the spring force applied by the biasing member 132.

[0089] More specifically, the trigger member 134 includes a tip retaining projection 136 which is adapted to engage an opening 138 formed through the tip body 126. This projection 136 is formed adjacent an inner end 140 of the trigger member 134 which is disposed within the needle housing 118. The tip retaining projection 136 extends from about the inner end 140 of the trigger member 134 towards an outer end 142 thereof where it engages the opening 138 of the tip body 126 mounted therebetween.

[0090] As briefly mentioned above, the outer end 142 of the trigger member 134 is exposed through the needle housing 118 and serves as a trigger mechanism for moving the tip body 126 toward the distal opening 144 of the groove 124. Due to its barb fitting arrangement with the sheath assembly 122, the movement of the tip body 126 effectuates the passive movement of the sheath assembly 122 from the retracted position 146 to the extended position (not shown).

[0091] The manner of repositioning the sheath assembly 122 to the extended position is accomplished through the release of the tip body 126 from the trigger member 134. Essentially, the tip retaining projection 136 of the trigger member 134 maintains the tip body 126 and the sheath assembly 122 in the retracted position 146 until the tip body 126 is manually released from the trigger member 134. This automatically triggers the tip body 126 and the sheath assembly 122 to move towards the extended position. Such release of the tip body 126 is performed by manually pushing in the outer end 142 of the trigger member 134 towards the needle housing 118. This causes the tip retaining projection 136 to slip out from the opening 138 and free the tip body 126 from its holding.

[0092] Because the biasing member 132 is mechanically connected to the tip body 126 to apply a spring force toward the distal opening 144 of the groove 124, the tip body 126 is automatically caused by the biasing member 132 to be urged in that direction and form the extended position. Due to its barb fitting connection with the proximal sheath end 128, the tip body 126 pushes the sheath assembly 122 towards the distal opening 144 of the groove 124.

This effectuates the sheath assembly 122 to be passively deployed outside of the needle housing 118 and form the extended position with respect to the distal portion 114 of the needle 116.

[0093] Similar to the above-described proximal tip component 76, the tip body 126 possesses a body size which is substantially larger than the distal opening 144 of the groove 124. Because of its larger body size, the tip body 126 is forced to stop once it reaches and abuts the portion of the groove 124 which converges inwardly to narrow the distal opening 144 thereof. However, the size of the distal opening 144 is sufficiently large enough to allow the sheath assembly 122 to pass therethrough and be deployed outside of the needle housing 118 to extend over the entirety of the distal needle portion 114. The sheath assembly 122 remains in this outwardly deployed configuration as the spring force of the biasing member 132 continuously urges the tip body 126 against the converged portion of the groove 124 which forms its narrowed distal opening 144.

[0094] Referring now to Figures 17 and 19, there is shown another passive safety needle device 150 which is constructed in accordance with a third preferred embodiment of the present invention. The passive safety needle device 150 of the third embodiment is essentially a modified version of the previously defined needle devices 10, 110 and is designed to perform the same function (i.e., deter needle-stick injuries). However, as will be explained below, a different sheath releasing concept is employed for covering the needle 152 in order to protect its users against the dangers of needle-stick injuries.

[0095] But prior to describing the specifics of such unique sheath releasing concept, it should be briefly pointed out herein that the needle housing 154 of the third embodied safety needle device 150 may optionally comprise a layer of padding 156 underneath so as to increase its user-friendliness (e.g., provide softening cushion upon user's chest) during needle applications. However, this is strictly an optional feature, and is not absolutely necessary as exemplified in the safety needle devices 10, 110 of the first and second embodiments.

[0096] In particular, the layer of padding 156 is attached underneath a platform 158 of the needle housing 154 and further conforms to the configuration thereof. Preferably, it is adhered thereto via an adhesive (e.g., glue or bond) but a person of ordinary skill in the art will contemplate that other types of attachment means may be used instead. Although various materials may be used to fabricate this layer of padding 156, it is preferably made from a foam material, and more preferably a closed-cell foam material.

[0097] Turning now to the additional uniqueness of the third embodiment, Figures 18 and 19 show an overall sheath releasing mechanism which specifically eliminates the need for any type of proximal tip component 76 such as a ferrule (as used in the first preferred embodiment) or a tip body 126 (as used in the second preferred embodiment). More specifically, the safety needle device 150 of the third embodiment is capable of retaining, releasing and moving the sheath assembly 160 along the needle housing's groove 162 without using those components at the proximal sheath end 164.

[0098] Instead, the passive safety needle device 150 of the third embodiment operates to move the sheath assembly 160 from a retracted position 166 to an extended position 168 directly with its biasing member 170, preferably a torsional arm. More specifically, this biasing member 170 forms an extension 172 which extends outwardly therefrom in a substantially parallel relationship with respect to the inner housing surfaces 174 of the needle housing towards the proximal end 164 of the sheath assembly 160. Upon reaching the proximate location of the proximal sheath end 164, an end portion 176 of the extension 172 is curved or bent generally perpendicular with respect to the inner housing surfaces 174 toward the proximal sheath end 164. The extension's end portion 176 is then connected through the proximal sheath end 164.

[0099] More specifically, the end portion 176 of the extension 172 becomes connected to the proximal sheath end 164 by being inserted through one particular side of the proximate sheath end 164. Although the end portion 176 may be retained within the proximal sheath end 164 for connection, it is preferably inserted all the way therethrough so as to extend out of the generally opposing side of the proximal sheath end 164. The end portion 176 of the extension 172 is then curved or bent backward in the general direction of the biasing member 170. This helps to prevent the end portion 176 from unintentionally slipping out or disconnecting from the proximal end 164 of the sheath assembly 160 unless that end 164 becomes torn or ruptured. In this manner, the biasing member 170 and the sheath assembly 160 become mechanically connected with each other.

[0100] As specifically illustrated in Figure 19, the safety needle device 150 of the third embodiment also employs the use of a trigger member 178 for retaining and releasing the sheath assembly 160. Similar to the version used in the second embodiment, the trigger member 178 utilized in the third embodiment has an inner end 180 disposed within the needle housing 154 and an outer end 182 disposed outside thereof. Likewise, this trigger member 178 is also

operative to release the retracted sheath assembly 160 when the user presses the exposed outer end 182 towards the needle housing 154. Upon such manual activation, the torsional force produced by the biasing member 170 inevitably causes the sheath assembly 160 to automatically slide along the groove 164 and form the extended position 168 over the needle 152.

[0101] Figure 19 further shows a tip retaining projection 184 which is formed adjacent the inner end 180 of the trigger member 178. As can be seen from that figure, the tip retaining projection 184 utilized in the third preferred embodiment is structurally different from its counterpart version used in the second embodiment. Such structurally distinguishable features allow the tip retaining projection 184 to directly engage the end portion 176 of the biasing member's extension 172 when the extension 172 and proximal sheath end 164 are maintained in the retracted position 166.

[0102] The tip retaining projection 184 utilized in the third embodiment extends upward and away from the inner end 180 of the trigger member 178. At the end of such extension, the tip retaining projection 184 defines a projected end 186 forming an engaging portion 188 which corresponds to the end portion 176 of the extension 172 and directly engages therewith. Specifically, this engaging portion 188 is in general perpendicular disposition relative to the projected end 186 of the tip retaining projection 184 and further comprises a notch 190 which faces or opens up toward the trigger member 178. The notch 190 is used for releasibly engaging the end portion 176 of the biasing member's extension 172 until the trigger member 178 is manually pressed toward the needle housing 154.

[0103] Preferably, the notch 190 of the engaging portion 188 is designed and used to hook a section of the extension's end portion 176 which is defined either prior or subsequent to the insertion into proximal sheath end 164. To facilitate the release of the extension 172, the notch 190 is formed of a smooth and continuous surface so as to allow the extension's end portion 176 to be easily dislodged therefrom without being caught or interfered by any surface configuration.

[0104] Upon the dislodging of the end portion 178, the sheath assembly 160 is caused to be outwardly deployed. The proximate sheath end 164 is designed to stop once reaching the distal opening 192 of the needle housing's groove 162. More specifically, the proximal sheath end 164 is inevitably stopped in such position as the extension 172 of the biasing member 170 comes in contact with the lower inner housing surface 194 of the needle housing 154. Such contact of the

extension 172 would forcibly stop the sliding movement of the sheath assembly 160 along the groove 162.

[0105] Due to the engagement of the extension 172 with the proximal sheath end 164, the extension 172 in turn forces the sheath assembly 160 to stop its movement when the proximal sheath end 164 reaches about the distal opening 192 of the groove 162. Such specified configuration results in the sheath assembly 160 to be deployed outside the needle housing 154 and be extended over the entirety of the needle 152. Of course, the assembly 160 should be sufficiently sized and elongated to cover the entirety of the exposed needle 152. The sheath assembly 160 should remain outwardly deployed in that position since the spring force of the biasing member 170 urges its extension 172 tightly against the lower inner housing surface 194 of the needle housing 154.

[0106] With the structure defined, the operation of the safety needle device 10 of the first embodiment is described herein to essentially illustrate the operation of the safety needle device 110 of the second and third embodiments as well. The safety needle device 10 of the first embodiment is designed for the purpose of protecting a user from getting stuck when withdrawing the needle 16 from the patient. Initially, a user grabs the exterior of the housing having the distal needle point extending downwardly therefrom. The distal needle point 42 is then inserted into a designated skin area of the patient to access the implanted IV port. By such penetration, various tasks such as delivering fluids and medications, drawing blood for diagnostic testing and/or infusing blood products may be conducted. Optionally, the safety needle device 10 of the present invention can be secured in place by taping its radially extending platform strips 62 to the patient's surrounding skin area.

[0107] After performing any one of the tasks as described above, the needle 16 is withdrawn from the patient. While withdrawing the needle 16, the externally disposed knob member 92 is manipulated by the user to manually control the outward deployment of the sheath assembly 64 from its retracted position 66 to its extended position 68. Such movement is further facilitated by the torsional spring 82. When the sheath assembly 64 travels to its extended position 68, the sheath surrounds and covers the distal needle portion and needle tip thereby preventing any inadvertent needle stick to the user. In the case of the safety needle device of the second or third embodiment 110 or 150, the outward deployment of the sheath assembly 122 or 160 can take

place by the manual pressing of the trigger member 134 or 178 which automatically triggers such deployment to occur.

[0108] The safety needle device 10 of the present invention is then ready for proper disposal. Preferably, the used safety needle device 10 is thrown away in a Sharps container which is designated for used medical devices.

[0109] Additional modifications and improvements of the present invention may also be apparent to those of ordinary skill in the art. Thus, the particular combination of parts described and illustrated herein is intended to represent only certain embodiments of the present invention, and is not intended to serve as limitations of alternative devices within the spirit and scope of the invention.